CLAIMS

1. A method for obtaining antigen-specific antibodies to a target bacterial carbohydrate antigen selected from among lipo-polycarbohydrate antigens, antigens comprising lipoteichoic acids or teichoic acid or derivatives of either, and capsular carbohydrate antigens, which comprises the steps of:

(a) purifying the target bacterial carbohydrate antigen to produce essentially protein-free antigen containing not more than about 10 percent of protein by weight,

(b) coupling said essentially protein-free antigen to a spacer molecule to produce a conjugate,

(c) coupling the conjugate from step (b) to an affinity gel to produce a further conjugate,

(d) passing raw polyclonal antibodies to the target bacterial antigen or an IgG cut thereof, over the further conjugate of step (c), and

(e) eluting from the further conjugate of step (c) purified antibodies specific to the crude target bacteria antigen.

2. Antigen-specific antibodies prepared by the method of Claim 1.

3. A method for assaying for the presence of target bacteria or a target carbohydrate antigen component thereof in a test sample comprising a fluid suspected of containing the target bacteria or their target carbohydrate antigen which method comprises contacting said test sample with antigen-specific antibodies to said target antigen produced by purifying raw polyclonal antibodies or an IgG cut thereof, according to the process of Claim 1.

4. The method of Claim 3 in which the test sample comprises a mammalian body fluid obtained from a mammalian patient suspected of harboring a disease caused by said target bacteria.

5. The method of Claim 4 in which the test sample comprises human urine obtained from a patient suspected of having a disease caused by the target bacteria.

6. A method according to Claim 5 in which the target bacteria are Gram-negative bacteria and their target antigen component is a lipo-polycarbohydrate.

7. A method according to claim 6 in which the lipo-carbohydrate is a lipo-polysaccharide.

8. A method according to Claim 5 in which the target bacteria are Gram-positive bacteria and their target antigen component is an antigen comprising a lipo-teichoic acid, a teichoic acid or a derivative of either.

9. A method according to Claim 5 in which the target bacteria is Gram-positive or Gram-negative and the target antigen is a capsular polycarbohydrate antigen.

10. A method according to Claim 9 in which the capsular polycarbohydrate antigen is a capsular polysaccharide antigen.

11. An ICT assay for the detection of target bacteria or their target carbohydrate antigen component, which comprises the steps of:

(a) contacting a sample of a fluid suspected of containing said target bacteria or their target carbohydrate antigen component with an ICT device comprising a strip of a bibulous material, which strip has

(i) a zone in which has been embedded a conjugate of:

(1) a labeling agent that displays a visible color change upon reaction of antibodies with their corresponding antigenic binding partner, and

(2) purified antigen-specific antibodies to the target carbohydrate antigen component, said antibodies having been purified by passage over a chromatographic affinity column to which is conjugated through a spacer molecule

the essentially protein-free purified target carbohydrate antigen component.

(ii) a second zone having bound thereto the same purified antigen-specific antibodies in unconjugated form, which zone is equipped with a window for viewing color changes;

(b) allowing said sample to flow laterally along said test strip to said first zone;

(c) allowing said sample, together with said conjugate of affinity purified antibodies and label, to flow laterally along said test strip to said second zone; and

(d) within approximately 15 to 20 minutes from the commencement of step (a), observing through said window whether a line of color has appeared in said second zone, thereby indicating the presence in the sample of the target bacteria or their target carbohydrate antigen component, or both, or whether no line of color has so appeared indicating the absence of the target bacteria and their target carbohydrate antigen component.

12. A method for obtaining an essentially protein-free carbohydrate or antigen component from Gram-positive or Gram-negative bacteria, which comprises the steps of:

(a) culturing the bacteria for a time requisite to obtain a sample of desired size and harvesting the bacterial cells therefrom in the form of a wet cell pellet;

(b) suspending the wet cell pellet in an alkaline solution and mixing;

(c) adjusting the pH to an acid pH with a strong acid and centrifuging;

(d) separating the supernatant from step (c) and adjusting its pH to approximate neutrality;

(e) digesting this product with a broad spectrum protease enzyme preparation to destroy residual proteins;

(f) adjusting the pH to the alkaline side with a weakly alkaline aqueous solution;

(g) separating out the essentially protein free carbohydrate antigen on a size exclusion column equilibrated with a weakly alkaline solution; and

(h) pooling material eluted in the first peak and adjusting its pH to approximate neutrality.

13. A method according to Claim 1 in which the target bacterial antigen is a capsular carbohydrate antigen of *Haemophilus influenzae* type b.

14. Antigen-specific antibodies according to Claim 2 which are specific to the capsular carbohydrate antigen of *Haemophilus influenzae* type b.

15. A method according to Claim 3 wherein the target bacteria are *Haemophilus influenzae* type b bacteria and their target carbohydrate antigen component is the capsular carbohydrate antigen of those bacteria.

16. The method of Claim 15 wherein the target bacteria are *Haemophilus influenzae* type b bacteria and their target carbohydrate antigen component is the capsular carbohydrate antigen of those bacteria.

17. The method of Claim 15 wherein the test sample comprises human urine.

18. The method of Claim 11 in which the target bacteria are *Haemophilus influenzae* type b bacteria, their target carbohydrate antigen components is a capsular carbohydrate antigen thereof, and the labeling agent is finely divided metallic gold.

19. A method according to Claim 12 in which the bacteria are *Haemophilus influenzae* type b bacteria and the essentially protein-free antigen component obtained is their essentially protein-free capsular carbohydrate antigen component.

20. A method according to Claim 3 in which the antigen-specific antibodies are present in a concentration of between 7.7 nanograms/sq. mm. of surface area and 385 nanograms/sq. mm. of surface area at each site of a test device at which antigen:antibody reaction is to occur.

21. A method according to Claim 11 in which the antigen-specific antibodies are present in a concentration of between 7.7 nanograms/sq. mm. of surface area and 385 nanograms/sq. mm. of surface area at each site of a test device at which antigen:antibody reaction is to occur.